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EXAMINER	
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ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,063	KOHARA ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10790063*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I in the reply filed on 1 June 2006 is acknowledged.

2. Claims 14-18 have been withdrawn. Claims 1-13 are under prosecution.

Information Disclosure Statement

The Information Disclosure Statement filed 1 March 2004 is acknowledged. However, documents 2000-346842 (Japan), 2002-117487 (Japan), and 11/243997 (Japan) are not being considered because English language translations of the documents have not been provided. See MPEP 609.

Claim Objections

Claim 7 is objected to because of the following informalities: claim 7 recites limitation "the given magnetic micros-particle" in line 3 of the claim. This appears to be a typographical error.. Appropriate correction is required.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1-13 are indefinite in claims 1 and 10, which recite the limitation "included in a in a given sequence" in lines 7-8 of each of claims 1 and 10. It is unclear if the recitation means the particles are added in a particular chronological order of if the recitation means the particles are in specific physical locations within the system. It is suggested the claim be amended to clarify the recitation.

2. Claims 2 and 4 are indefinite in claim 2, which recites the limitation "the magnetic micro-particles" at the end of claim 2. There is insufficient antecedent basis for "magnetic micro-particles" in "a magnetic micro-particle" (i.e., a singular particle) of claim 1. It is suggested the claim be amended to reflect proper antecedent basis.

3. Claims 10-13 are indefinite in claim 10, which recites the limitation "a probe binding to a particular molecule" in line 5 of claim 10. It is unclear if the probe is actively bound to the particular molecule when provided as a kit of if the probe is bound to a particular molecule during the course of using the kit.

4. Claim 13 is indefinite in the recitation "a channel provided in a capillary or a substrate" at the end of the claim. It is unclear if "a substrate" is an alternative to "a channel provided in a capillary" (i.e., does not require a channel) or if "a substrate" requires a channel.

Claim Rejections - 35 USC § 112 Sixth Paragraph

The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The limitations "introducing means" and "position-control means" as found in claims 1, 5, and 6 are not being treated under 35 USC 112, sixth paragraph because the Specification does not provide explicit limitations as to the means for providing the various functions found in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless--
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Cathcart et al (U.S. Patent No. 5,443,791, issued 22 August 1995).

Regarding claim 1, Cathcart et al teach a micro-particle array analyzing system comprising:

a vessel holding at least a non-magnetic micro-particle (e.g., an array of tubes containing DNA samples [i.e., the DNA molecules are the non-magnetic particles]; column 8, lines 1-3 and Figure 1);

introducing means for introducing a sample and a solution into the vessel (e.g., a pipette apparatus that is part of an automated system; Abstract);

a position-control means disposed outside of the vessel for magnetically controlling a relative position of the magnetic micro-particle with respect to the vessel (e.g., magnetic particle wash stations 26 and 29; column 8, lines 4-10 and Figure 1);

wherein the non-magnetic micro-particle is included in a given sequence within the vessel (e.g., DNA samples are in the tubes; column 17, lines 52-55).

With respect to the inclusion of the micro-particles within the vessel, the courts have held that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, the sequence of the particles recited in claim 1 (e.g., inclusion of the micro-particles in a given sequence within the vessel) fails to define additional structural elements to the system of claim 1. Because Cathcart et al teach the structural elements of claim 1, the claim is anticipated by Cathcart et al. See MPEP § 2113 [R-1].

Regarding claim 5, Cathcart et al teach the system of claim 1 wherein the position-control means is a magnet member movably provided outside the vessel (e.g., the automated laboratory has a movable magnet bar; column 5, lines 8-11).

2. Claims 1-3, 5, and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (U.S. Patent No 5,306,619, issued 26 April 1994).

Regarding claim 1, Edwards et al teach a micro-particle array analyzing system (column 1, lines 10-11) comprising:

a vessel (e.g., reaction tubes in a magnetic rack; column 15, lines 34-38) holding at least a magnetic micro particle (e.g., streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38) and/or at least a non-magnetic micro-particle (e.g., the particle is biotin, which is attached to DNA; column 3, lines 41-44 and column 15, lines 34-38); and

introducing means for introducing a sample and a solution into the vessel (e.g., the beads are added to binding buffer and the oligonucleotides; column 29, lines 30-32).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not posses characteristic relied on" (205 USPQ 594, second column, first full paragraph). Because Edwards et al teach the mixture is added to reaction tubes (column 15, lines 34-38 and column 29, lines 25-39), the system as taught by Edwards et al has introducing means for introducing a sample and a solution into the vessel (i.e., the reaction tubes have an opening that is the means for allowing introduction of the sample and the solution).

Edwards et al also teach a position-control means disposed outside of the vessel for magnetically controlling a relative position of the magnetic micro-particle with respect to the vessel (e.g., 96-well plate magnets for retrieving the beads; column 29, lines 35-39);

wherein the magnetic micro-particle and non-magnetic particle are included in a given sequence within the vessel (e.g., the beads are added to the binding mixture, which contains binding buffer and the biotinylated oligonucleotide; column 29, lines 30-32).

As noted above, with respect to the inclusion of the micro-particles within the vessel, the patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, the sequence of the particles recited in claim 1 (e.g., inclusion of the micro-particles in a given sequence within the vessel) fails to define additional structural elements to the system of claim 1. Because Edwards et al teach the structural elements of claim 1, the claim is anticipated by Edwards et al. See MPEP § 2113 [R-1].

Regarding claim 2, Edwards et al teach the system of claim 1, wherein the non-magnetic micro-particle has a probe immobilized to a surface thereof (e.g., the non-magnetic particle is biotin, which is linked to a oligonucleotide [column 3, lines 41-44 and column 15, lines 34-38], and is immobilized when the biotin is bound to the streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38),

and is included in the vessel (e.g., the biotinylated oligonucleotides are in the reaction tubes; column 15, lines 34-38 and column 29, lines 26-39) to be sandwiched between the magnetic micro-particles (e.g., the oligonucleotides are captured [i.e., sandwiched between] by the magnetic beads; column 29, lines 35-39).

Regarding claim 3, Edwards et al teach the system of claim 1, wherein a plurality of magnetic micro-particles are used (e.g., there is more than one bead present; column 29, lines 26-39) and at least one of the magnetic micro-particles has a probe immobilized to the surface thereof (e.g., the biotinylated DNA is immobilized when the biotin is bound to the streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38).

Regarding claim 5, Edwards et al teach the system of claim 1, wherein the position-control means is a magnet member movably provided outside of the vessel (e.g., the position-control means is a magnetic rack [96-well plate magnets], from Dynal [i.e., the 96-well plate magnet is a separate piece of equipment]; column 29, lines 35-39).

Regarding claim 10, Edwards et al teach a micro-particle array kit (column 1, lines 10-11) comprising:

a vessel (e.g., reaction tubes in a magnetic rack; column 15, lines 34-38) holding at least a magnetic micro-particle (e.g., streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38) and/or at least a non-magnetic micro-particle (e.g., the particle is biotin, which is attached to DNA; column 3, lines 41-44 and column 15, lines 34-38);

a magnet member disposed outside of the vessel (e.g., the position-control means is a magnetic rack [96-well plate magnets], from Dynal [i.e., the 96-well plate magnet is a separate piece of equipment]; column 29, lines 35-39); and

a probe binding to a particular molecule and being immobilized to any one of positions inside the vessel (e.g., the non-magnetic particle is biotin, which is linked to a oligonucleotide [column 3, lines 41-44 and column 15, lines 34-38], and is immobilized when the biotin is bound to the streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38),

wherein the magnetic micro-particle and non-magnetic particle are included in a given sequence within the vessel (e.g., the beads are added to the binding mixture, which contains binding buffer and the biotinylated oligonucleotide; column 29, lines 30-32).

As noted above, with respect to the inclusion of the micro-particles within the vessel, the patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, the sequence of the particles recited in claim 10 (e.g., inclusion of the micro-particles in a given sequence within the vessel) fails to define additional structural elements to the kit of claim 10. Because Edwards et al teach the structural elements of claim 10, the claim is anticipated by Edwards et al. See MPEP § 2113 [R-1].

Regarding claim 11, Edwards et al teach an alternative interpretation of claim 10 (i.e., a second interpretation applied to claim 11), wherein Edwards et al teach a micro-particle array kit (column 1, lines 10-11) comprising:

a vessel (e.g., reaction tubes in a magnetic rack; column 15, lines 34-38) holding at least a non-magnetic micro-particle (e.g., avidin coated agarose beads; column 15, lines 39-50);

a magnet member disposed outside of the vessel (e.g., the position-control means is a magnetic rack [96-well plate magnets], from Dynal [i.e., the 96-well plate magnet is a separate piece of equipment]; column 29, lines 35-39); and

a probe binding to a particular molecule and being immobilized to any one of positions inside the vessel (e.g., the non-magnetic particle is the avidin coated agarose bead [column 15, lines 39-50], wherein a biotinylated oligonucleotide [column 3, lines 41-44 and column 15, lines 34-38] is immobilized when the biotin is bound to the avidin-coated agarose beads; column 15, lines 39-50),

wherein the non-magnetic particle are included in a given sequence within the vessel (e.g., the beads are added to the binding mixture, which contains binding buffer and the biotinylated oligonucleotide; column 29, lines 40-45).

As noted above, with respect to the inclusion of the micro-particles within the vessel, the patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, the sequence of the particles recited in claim 10 (e.g., inclusion of the micro-particles in a given sequence

within the vessel) fails to define additional structural elements to the kit of claim 10. Because Edwards et al teach the structural elements of claim 10, the claim is anticipated by Edwards et al. See MPEP § 2113 [R-1].

Edwards et al also teach the kit wherein the probe is immobilized to the non-magnetic micro-particle (e.g., the non-magnetic particle is the avidin-coated agarose bead [column 15, lines 39-50], wherein a biotinylated oligonucleotide [column 3, lines 41-44 and column 15, lines 34-38] is immobilized when the biotin is bound to the avidin-coated agarose beads; column 15, lines 39-50).

Regarding claim 12, Edwards et al teach the kit of claim 10 (i.e., the first interpretation detailed above), wherein the probe is immobilized to the magnetic micro-particle (e.g., the biotinylated DNA is immobilized when the biotin is bound to the streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38).

Regarding claim 13, Edwards et al teach the kit of claim 10 (i.e., the first interpretation detailed above), wherein the vessel is a substrate (e.g., a reaction tube; column 15, lines 34-38).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1, 2, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (U.S. Patent No 5,306,619, issued 26 April 1994) in view of Cathcart et al (U.S. Patent No. 5,443,791, issued 22 August 1995).

Regarding claim 4, Edwards et al teach the micro-particle array analyzing system (column 1, lines 10-11) of claim 1 comprising:

a vessel (e.g., reaction tubes in a magnetic rack; column 15, lines 34-38) holding at least a magnetic micro particle (e.g., streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38) and/or at least a non-magnetic micro-particle (e.g., the particle is biotin, which is attached to DNA; column 3, lines 41-44 and column 15, lines 34-38); and

introducing means for introducing a sample and a solution into the vessel (e.g., the beads are added to binding buffer and the oligonucleotides; column 29, lines 30-32).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not posses characteristic relied on" (205 USPQ 594, second column, first full paragraph). Because Edwards et al teach the mixture is added to reaction tubes (column 15, lines 34-38 and column 29, lines 25-39), the system as taught by Edwards et al has introducing means for introducing a sample and a solution into the vessel (i.e., the reaction tubes have an opening that is the means for allowing introduction of the sample and the solution).

Edwards et al also teach a position-control means disposed outside of the vessel for magnetically controlling a relative position of the magnetic micro-particle with respect to the vessel (e.g., 96-well plate magnets for retrieving the beads; column 29, lines 35-39);

wherein the magnetic micro-particle and non-magnetic particle are included in a given sequence within the vessel (e.g., the beads are added to the binding mixture, which contains binding buffer and the biotinylated oligonucleotide; column 29, lines 30-32).

As noted above, with respect to the inclusion of the micro-particles within the vessel, the patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, the sequence of the particles recited in claim 1 (e.g., inclusion of the micro-particles in a given sequence within the vessel) fails to define additional structural elements to the system of claim 1. Because Edwards et al teach the structural elements of claim 1, the claim is anticipated by Edwards et al. See MPEP § 2113 [R-1].

Edwards et al also teach the system of claim 2, wherein the non-magnetic micro-particle has a probe immobilized to a surface thereof (e.g., the non-magnetic particle is biotin, which is linked to a oligonucleotide [column 3, lines 41-44 and column 15, lines 34-38], and is immobilized when the biotin is bound to the streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38),

and is included in the vessel (e.g., the biotinylated oligonucleotides are in the reaction tubes; column 15, lines 34-38 and column 29, lines 26-39) to be sandwiched between the magnetic micro-particles (e.g., the oligonucleotides are captured [i.e., sandwiched between] by the magnetic beads; column 29, lines 35-39); and

a detector for detecting a bond between the probe and organism-related molecules included in the sample (e.g., the system includes means for detecting the amount of binding protein [i.e., an organism-related molecule] bound to the DNA; column 3, lines 64-66).

While Edwards et al teach the analysis of data produced by the system (column 19, lines 65-67), Edwards et al do not teach an analyzer for analyzing the results of detection.

However, Cathcart et al teach a micro-particle array analyzing system comprising:

a vessel holding at least a non-magnetic micro-particle (e.g., an array of tubes containing DNA samples [i.e., the DNA molecules are the non-magnetic particles]; column 8, lines 1-3 and Figure 1);

introducing means for introducing a sample and a solution into the vessel (e.g., a pipette apparatus that is part of an automated system; Abstract);

a position-control means disposed outside of the vessel for magnetically controlling a relative position of the magnetic micro-particle with respect to the vessel (e.g., magnetic particle wash stations 26 and 29; column 8, lines 4-10 and Figure 1); and

an analyzer for analyzing the results of detection (e.g., the system receives analyzed data from a scanner; column 29, lines 45-50) with the added advantage that the results are accomplished in a simple and more rapid manner that the manual methods typically employed (column 29, lines 50-55).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the system as taught by Edwards et al with the analyzer as taught by Cathcart et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in results that are accomplished in a simple and more rapid manner that the manual methods typically employed as explicitly taught by Cathcart et al (column 29, lines 50-55).

3. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (U.S. Patent No 5,306,619, issued 26 April 1994) in view of Lea et al (U.S. Patent No. 5,681,478, issued 28 October 1997).

Regarding claim 6, Edwards et al teach the micro-particle array analyzing system (column 1, lines 10-11) of claim 1 comprising:

a vessel (e.g., reaction tubes in a magnetic rack; column 15, lines 34-38) holding at least a magnetic micro particle (e.g., streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38) and/or at least a non-magnetic micro-particle (e.g., the particle is biotin, which is attached to DNA; column 3, lines 41-44 and column 15, lines 34-38); and

introducing means for introducing a sample and a solution into the vessel (e.g., the beads are added to binding buffer and the oligonucleotides; column 29, lines 30-32).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not posses characteristic relied on" (205 USPQ 594, second column, first full paragraph). Because Edwards et al teach the mixture is added to reaction tubes (column 15, lines 34-38 and column 29, lines 25-39), the system as taught by Edwards et al has introducing means for introducing a sample and a solution into the vessel (i.e., the reaction tubes have an opening that is the means for allowing introduction of the sample and the solution).

Edwards et al also teach a position-control means disposed outside of the vessel for magnetically controlling a relative position of the magnetic micro-particle with respect to the vessel (e.g., 96-well plate magnets for retrieving the beads; column 29, lines 35-39);

wherein the magnetic micro-particle and non-magnetic particle are included in a given sequence within the vessel (e.g., the beads are added to the binding mixture, which contains binding buffer and the biotinylated oligonucleotide; column 29, lines 30-32).

As noted above, with respect to the inclusion of the micro-particles within the vessel, the patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, the sequence of

the particles recited in claim 1 (e.g., inclusion of the micro-particles in a given sequence within the vessel) fails to define additional structural elements to the system of claim 1. Because Edwards et al teach the structural elements of claim 1, the claim is anticipated by Edwards et al. See MPEP § 2113 [R-1].

Edwards et al are silent with respect to electromagnets.

However, Lea et al teach separation of magnetic particles using a system (i.e., an apparatus; Title) using electromagnets (Abstract) wherein the magnets control capturing (e.g., separation and re-suspension; column 2, lines 31-40) with the added advantage that electromagnets allow the strengths of the magnetic fields to be varied with respect to the time that they are being applied (column 2, lines 18-20).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the system as taught by Edwards et al with the electromagnets as taught by Lea et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing the strengths of the magnetic fields to be varied with respect to the time that they are being applied as explicitly taught by Lea et al (column 2, lines 18-20).

4. Claims 1 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (U.S. Patent No 5,306,619, issued 26 April 1994) in view of Harrison et al (U.S. Patent No. 6,432,290 B1, issued 13 August 2002).

Regarding claim 7, Edwards et al teach the micro-particle array analyzing system (column 1, lines 10-11) of claim 1 comprising:

a vessel (e.g., reaction tubes in a magnetic rack; column 15, lines 34-38) holding at least a magnetic micro particle (e.g., streptavidin-coated superparamagnetic polystyrene beads; column 15, lines 34-38) and/or at least a non-magnetic micro-particle (e.g., the particle is biotin, which is attached to DNA; column 3, lines 41-44 and column 15, lines 34-38); and

introducing means for introducing a sample and a solution into the vessel (e.g., the beads are added to binding buffer and the oligonucleotides; column 29, lines 30-32).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not posses characteristic relied on" (205 USPQ 594, second column, first full paragraph). Because Edwards et al teach the mixture is added to reaction tubes (column 15, lines 34-38 and column 29, lines 25-39), the system as taught by Edwards et al has introducing means for introducing a sample and a solution into the vessel (i.e., the reaction tubes have an opening that is the means for allowing introduction of the sample and the solution).

Edwards et al also teach a position-control means disposed outside of the vessel for magnetically controlling a relative position of the magnetic micro-particle with

respect to the vessel (e.g., 96-well plate magnets for retrieving the beads; column 29, lines 35-39);

wherein the magnetic micro-particle and non-magnetic particle are included in a given sequence within the vessel (e.g., the beads are added to the binding mixture, which contains binding buffer and the biotinylated oligonucleotide; column 29, lines 30-32).

As noted above, with respect to the inclusion of the micro-particles within the vessel, the patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, the sequence of the particles recited in claim 1 (e.g., inclusion of the micro-particles in a given sequence within the vessel) fails to define additional structural elements to the system of claim 1. Because Edwards et al teach the structural elements of claim 1, the claim is anticipated by Edwards et al. See MPEP § 2113 [R-1].

Edwards et al are silent with respect to branched channels.

However, Harrison et al teach a vessel (i.e., an on-chip reactor bed; Abstract) comprising branched channels (Figure 10) wherein magnetic particles are included in a channel and are taken out from an open end of the channel (e.g., side channels allow the flushing of beads [column 14, lines 52-57], wherein the beads are magnetic; column 12, line 60) with the added advantage that exhausted beads are removed and replaced with fresh ones (column 14, lines 8-12).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the system as taught by Edwards et al with the channels as taught by Harrison et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in the ability to remove exhausted beads and replace them with fresh ones as explicitly taught by Harrison et al (column 14, lines 8-12).

Regarding claim 8, the system of claim 1 is discussed above. Edwards et al do not teach a transporting mechanism or an electrophoresis apparatus.

However, Harrison et al teach a vessel (i.e., an on-chip reactor bed; Abstract) comprising channels (Figure 10) and magnetic micro-particles (column 12, line 60), having a transport mechanism for collecting the micro-particles from an opening end of the vessel (e.g., the chip pumps the beads [i.e., micro-particles] electrokinetically [column 7, lines 30-40], wherein side channels [i.e., an opening end of the vessel] allow the flushing of beads; column 14, lines 52-57) and an electrophoresis apparatus connected to the transport mechanism (e.g., a power supply and relay system for electrophoretic voltages for liquid handling; column 6, line 66-column 7, line 5) with the added advantage that the transport mechanism allows exhausted beads to be removed from the side channel (i.e., an opening end of the vessel) and replaced with fresh ones (column 14, lines 8-12).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the system as taught by Edwards et al with the transport mechanism as taught by Harrison et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in the ability to remove exhausted beads and replace them with fresh ones as explicitly taught by Harrison et al (column 14, lines 8-12).

Regarding claim 9, the system of claim 1 is discussed above. Edwards et al do not teach a transporting mechanism or a mass spectroscope.

However, Harrison et al teach a vessel (i.e., an on-chip reactor bed; Abstract) comprising channels (Figure 10) and magnetic micro-particles (column 12, line 60), having a transport mechanism for collecting the micro-particles from an opening end of the vessel (e.g., the chip pumps the beads [i.e., micro-particles] electrokinetically [column 7, lines 30-40], wherein side channels [i.e., an opening end of the vessel] allow the flushing of beads; column 14, lines 52-57) and a mass spectroscope (i.e., spectrometer; Figure 10) with the added advantage that the transport mechanism allows exhausted beads to be removed from the side channel (i.e., an opening end of the vessel) and replaced with fresh ones (column 14, lines 8-12).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the system as taught by Edwards

et al with the transport mechanism as taught by Harrison et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in the ability to remove exhausted beads and replace them with fresh ones as explicitly taught by Harrison et al (column 14, lines 8-12).

Conclusion

1. No claim is allowed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER 7/21/06